

APR 2 | 1999

UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

Norman H. Stepno Burns, Doane, Swecker & Mathis, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404

In re

Centre International de Recherches Dermatologiques

U.S. Patent No. Re. 34,440 DIFFERIN SOLUTION

DISMISSAL OF PATENT

TERM EXTENSION

APPLICATION

RE: DIFFERIN SOLUTION

FDA Docket No.: 96E-0362

An application for patent term extension of U.S. Patent Re. 34,440 based upon the human drug product DIFFERIN SOLUTION (adapalene) was filed by Centre International de Recherches Dermatologiques in the Patent and Trademark Office on July 26, 1996. Applications for patent term extension of U.S. Patent Nos. Re. 34,440, 4,717,720, 5,015,758, and 5,212,303 were also filed based upon the regulatory review of the product DIFFERIN Gel (adapalene), and of U.S. Patent Nos. Re. 4,717,720, 5,015,758 and 5,212,303 based upon the regulatory review of the product DIFFERIN Solution (adapalene) on July 26, 1996.

On February 24, 1999, the PTO mailed a Notice of Final Determination in the above-noted application informing applicant that the patent qualifies for patent term extension but for the fact that only one patent may be extended for the same regulatory review period for a product. See 35 U.S.C. § 156(c)(4). Applicant was given a period of one-month to elect the patent for which term extension was desired for each regulatory review period.

On March 14, 1999, applicant filed a paper electing to have the term of U.S. Patent No. 4,717,720 extended based upon the regulatory review period of DIFFERIN SOLUTION and a second paper electing to have the term of U.S. Patent No. Re. 34,440 extended based upon the regulatory review period of DIFFERIN GEL. Accordingly, the application for patent term extension of the term of U.S. Patent No. Re. 34,440 based upon DIFFERIN SOLUTION is dismissed under 35 U.S.C. 156(c)(4).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson, Senior Legal Advisor

Special Program Law Office, Office of the DAC for Patent Policy and Projects

cc: Ronald L. Wilson, Director

Health Assessment Policy Staff

Office of Health Affairs (HFY-20) Food and Drug Administration

5600 Fishers Lane, Room 15-22

Rockville, MD 20857